



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Graham Smith  
Serial No. : 09/986,392  
Filed : November 8, 2001  
Title : TISSUE REPAIR SYSTEM

Art Unit : 3732  
Examiner : Unknown

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DECLARATION OF GRAHAM SMITH UNDER 37 C.F.R. § 1.131

1. I am the sole inventor of the subject matter claimed in claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31 of the above-captioned U.S. Patent Application No. 09/986,392 ("the '392 application").

2. I am now, and have been during all times discussed in this Declaration, an employee of Smith & Nephew, Inc. ("Smith & Nephew"), the assignee of the '392 application. During the time period discussed in this Declaration, I worked at Smith & Nephew's facilities in Andover, Massachusetts and in the United Kingdom.

3. Prior to April 30, 2001, I conceived of the tissue repair system and method claimed in claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31 of the '392 application, as shown by an invention disclosure and drawings attached as Exhibit 1. On page 1, the entries for "date the idea first came to mind" and "date on which the idea was first reduced to writing in whole or in part" were prior to April 30, 2001, and have been redacted. On page 2, the dates next to the signatures of Graham Smith and Karen Drucker were after April 30, 2001, and have been redacted. On the remaining pages, the dates next to the signatures of Graham Smith and Paul Humby were prior to April 30, 2001, and have been redacted. The invention disclosure and drawings describe the tissue repair system and method claimed in claims 1-9, 12-15, 17, 19, 21-24, 28, 29, and 31 the '392 application, as follows:

a) With respect to claim 1, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body

includes a generally stationary restrictor ('A') configured to selectively restrict movement of a flexible member (i.e., the suture) coupled thereto such that after implantation, the flexible member can be moved through the restrictor in a first direction while, without the aid of an enlarged portion on the flexible member, movement in a second, opposite direction can be restricted.

b) With respect to claim 2, the restrictor is configured to engage the flexible member to selectively restrict movement of the flexible member. With respect to claim 3, the restrictor is configured to engage the flexible member at a substantially arbitrary position along a length of the flexible member. With respect to claim 4, the anchor body defines an opening through which the flexible member can be moved. With respect to claim 5, the restrictor is configured to engage the flexible member to selectively restrict passage of the flexible member through the opening. With respect to claim 6, the restrictor defines at least a part of the opening. With respect to claim 7, the restrictor defines a narrower portion of the opening than another portion of the opening. With respect to claim 8, the restrictor includes a sloped surface configured to compress the flexible member to permit passage of the flexible member through the opening. With respect to claim 9, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the opening.

c) With respect to claim 12, the anchor body includes a pair of legs. With respect to claim 13, the anchor body includes a bone-engaging ridge for retaining the bone anchor in a bone hole. With respect to claim 14, the anchor body is a unitary body. With respect to claim 15, the anchor body includes a post ('B') about which the flexible member is positionable.

d) With respect to claim 17, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') configured to receive a flexible member (i.e., the suture) such that after implantation of the anchor body within bone, the flexible

member can be moved through the restrictor while, without the aid of an enlarged portion on the flexible member, subsequent movement of the flexible member can be restricted. With respect to claim 28, the restrictor includes a sloped surface configured to compress the flexible member to permit passage of the flexible member through the first restrictor. With respect to claim 29, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the restrictor.

e) With respect to claim 19, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') defining a one-way passage configured to pass a suture in a first direction and restrict passage of the suture in a second, opposite direction. With respect to claim 21, the restrictor includes a sloped surface configured to compress the suture to permit passage of the suture through the one-way passage. With respect to claim 22, the restrictor includes opposing edges for engaging the flexible member to restrict passage of the flexible member through the one-way passage.

f) With respect to claim 23, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone. The anchor body includes a generally stationary restrictor ('A') defining an opening having a first portion for permitting passage of a member therethrough, and a second portion restricting passage of the member therethrough without the aid of an enlarged portion on the member.

g) With respect to claim 24, the figures on pages 2 and 3 illustrate a method including placing an anchor in bone, the anchor including a generally stationary restrictor ('A'); moving a flexible member (i.e., the suture) through the restrictor in a first direction (in the direction of the arrows on page 2), and restricting movement of the flexible member through the restrictor in a second, opposite direction (in the direction opposite the arrows on page 2).

h) With respect to claim 31, the figure on page 3 discloses a bone anchor including an anchor body configured to be retained within bone and to selectively restrict movement of a flexible member (i.e., the suture) coupled thereto. The anchor body defines an opening bounded by a sloped wall ('A'). The sloped wall is configured to compress the flexible member to permit passage of the flexible member through the opening in a first direction. The sloped wall includes a portion configured to engage the flexible member to restrict passage of the flexible member through the opening in a second, opposite direction.

4. From just before April 30, 2001 through the November 8, 2001 filing date of the '392 application, the following individuals employed and retained by Smith & Nephew and I diligently worked on preparation of the '392 application: Marie Concemi and Malcolm Wright, employees of Smith & Nephew, and Phyllis Kristal, John Conroy, and Peter Devlin of Fish & Richardson P.C., the legal representative of Smith & Nephew for the '392 application. This work is evidenced by at least the following:

a) In a memorandum from Ms. Concemi to Mr. Wright, dated April 17, 2001 (attached as Exhibit 2), Ms. Concemi requested that Mr. Wright conduct a prior art search based upon my invention disclosure and drawings. The dates next to the signatures of Graham Smith and Paul Humby were prior to April 30, 2001 and have been redacted. In an e-mail from Mr. Wright to Ms. Concemi dated April 25, 2001 (attached as Exhibit 3), Mr. Wright confirmed that he started the search. In a memorandum from Mr. Wright to Ms. Concemi, dated May 1, 2001 (attached as Exhibit 4), Mr. Wright provided the search results to Ms. Concemi.

d) In a letter from Ms. Concemi to Ms. Kristal, dated May 8, 2001 (attached as Exhibit 5), Ms. Concemi requested that Ms. Kristal evaluate my invention disclosure and drawings for purposes of filing a patent application.

e) Between May 8, 2001 and November 8, 2001, I assisted Ms. Kristal and Mr. Conroy in preparing the '392 application. For example, I sent facsimile transmissions with additional drawings to Mr. Conroy (attached as Exhibit 6). Note that in Exhibit 6 Mr. Conroy's surname is misspelled as "Cony" in some places. I also reviewed drafts of the application sent to me by Ms. Kristal (attached as Exhibit 7).

5. I have reviewed all of the documents attached as exhibits to this Declaration, and to the best of my knowledge and belief, the attached documents are true and correct copies of the originals.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

March 18<sup>th</sup>, 2004  
Date

  
Graham Smith